

PATENT COOPERATION TREATY

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From the
INTERNATIONAL SEARCHING AUTHORITY

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To:

see form PCT/ISA/220

12/5

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2004/036339

International filing date (day/month/year)
01.11.2004

Priority date (day/month/year)
31.10.2003

International Patent Classification (IPC) or both national classification and IPC
A61M5/32, A61M25/06

Applicant
TYCO HEALTHCARE GROUP LP

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/036339

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/036339

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-26,32,35-40
	No: Claims	27-31,33,34
Inventive step (IS)	Yes: Claims	1-26,32,35-40
	No: Claims	27-31,33,34
Industrial applicability (IA)	Yes: Claims	1-40
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2004/036339

Re Item V.

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1 Reference is made to the following documents:

D1 : US 2002/193745 A1 (FERGUSON F. MARK) 19 December 2002,
D2 : EP 0 750 915 A (JOHNSON & JOHNSON MEDICAL, INC) 2 January 1997,
D3 : US 6 616 630 B1 (WOEHR KEVIN ET AL) 9 September 2003,
D4 : US 5 053 017 A (CHAMUEL ET AL) 1 October 1991,
D5 : US 2002/151850 A1 (FERGUSON F. MARK ET AL) 17 October 2002,
D6 : WO 96/22800 A (DEVON INDUSTRIES, INC) 1 August 1996 (1996-08-01).

2 INDEPENDENT CLAIM 27

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 27 is not new in the sense of Article 33(2) PCT.

The reasons are the following:

2.2 Document D1 discloses (the references in parenthesis applying to this document) all the features of independent claim 27, namely:

"A medical clip (see fig. 2, 3, 6, ref. sign 18) adapted for use with a piercing member (see fig. 2, 6, ref. sign 16) having a distal end (see fig. 2, 3, 6, ref. sign 14) and defining a longitudinal axis, the clip comprising:

a first cavity (see fig. 3, ref. sign 20) dimensioned for movement of the piercing member therethrough and being oriented in an axis transverse to the longitudinal axis of the piercing member, the first cavity being rotatable (see and compare fig. 2, 6, ref. sign 18), relative to the longitudinal axis of the piercing member, between a movable orientation (see fig. 2, ref. sign 18) and a binding orientation (see fig. 6, ref. sign 18);

a first leg (see fig. 2, 3, 6, ref. sign 24) that defines a distal part (see fig. 2, 3, 6, ref. sign 36) extending therefrom and a second cavity (see aperture in the distal end 36 in fig. 2, 3, 6), the second cavity being disposed distal to the first cavity and dimensioned for movement of the piercing member therethrough; and

a second leg (see fig. 2, 3, 6, ref. sign 26) having a surface (see the distal end of the second leg 26 in fig. 2, 6) configured to engage the piercing member,

wherein the first leg and the second leg are, relative to the first and second legs,

biased for convergent movement (see and compare fig. 2, 6, ref. sign 24, 26) such that the first cavity is disposed in the binding orientation upon movement of the piercing member out of the second cavity".

- 2.3 Furthermore, the documents D2 (see fig. 6 and 7), D3 (see fig. 4A and 4B) and D4 (see fig. 1 to 4) also disclose all the features of claim 27.

Hence, the subject-matter of claim 27 is not novel (Article 33(2) PCT).

3 DEPENDENT CLAIMS 28-37

- 3.1 Dependent claims 28 to 31, 33 and 34 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (Article 33(2) PCT), the reasons being as follows:

- 3.2 All the features of dependent claims 28 to 31, 33 and 34 are already known, see for example:

- D1, fig. 3, ref. signs 18, 20, 24, 26 (relevant to claim 28),
- D1, fig. 3, ref. signs 20, 22, fig. 2, 6, par. 56 (relevant to claims 29, 30, 33, 34),
- D1, fig. 2, 3, ref. sign 36 (relevant to claim 31),
- D2, fig. 6, 7 (relevant to claims 28 to 31, 33, 34).

Hence, the features of dependent claims 28 to 31, 33 and 34 are not apt to render the subject-matter of independent claim 1 in combination with the features of any claim to which they refer novel (Article 33(2) PCT).

- 3.3 The combination of the features of dependent claims 32 and 35 to 37 seem neither to be known from, nor rendered obvious by, the available prior art.

4 INDEPENDENT CLAIMS 1, 15, 40

- 4.1 Document D5 discloses (the references in parenthesis applying to this document) in

figures 22 and 24 a safety shield comprising a piercing member (16) and a clip (22"). The clip defines a first cavity, a first leg having a second cavity and further having a distal part that engages with a medical device. The first and second leg are biased for divergent movement (compare fig. 22 and fig. 24).

- 4.2 Document D6 discloses (the references in parenthesis applying to this document) in figures 25 to 27 a safety shield comprising a piercing member (132) and a clip (348). The clip defines a first cavity (362), a second leg (356) and a first leg (360) having a second cavity (364) and a distal part (354) engaging a medical device (222). The form of the clip is maintained in both orientations (compare fig. 25 and 26), the movable orientation (see fig. 25) and the binding orientation (see fig. 26).
- 4.3 The subject-matter of corresponding independent claims 1, 15 and 40 differ from the safety shield known from the documents D5 and D6 in that the second leg comprises a bearing surface that engages the piercing member and in that the first leg and the second leg are biased for convergent movement such that the first cavity is disposed in the binding orientation and the distal part of the first leg disengages the medical device (for full definition, see corresponding claims 1, 15 and 40).
- 4.4 The problem to be solved by the present invention may be regarded to provide a safety shield that is efficiently manufactured due to a less complicated design (see page 2, paragraph 3).
- 4.5 None of the cited documents hint to the solution as defined in the corresponding independent claims 1, 15 and 40 in order to solve the problem posed.
- 4.6 The solution according to the corresponding independent claims 1, 15 and 40 of the present application is considered as being novel (Article 33(2) PCT), involving an inventive step (Article 33(3) PCT) and being industrially applicable (Article 33(4) PCT).
- 4.7 Claims 2 to 14, 23 to 25, 38 and 39 are dependent on claim 1 and claims 16 to 19, 21 and 22 are dependent on claim 15, said dependent claims as such also meet the requirements of the PCT with respect to novelty and inventive step and industrial applicability.

5 INDEPENDENT CLAIM 20, 26

- 5.1 Document D5 discloses (the references in parenthesis applying to this document) in figures 22 and 24 a safety needle shield comprising a piercing member (16) and a clip (22"). The clip defines a first cavity, a first leg having a second cavity and further having a distal part that engages with a medical device. The first and second leg are biased for divergent movement (compare fig. 22 and fig. 24).
- 5.2 Document D6 discloses (the references in parenthesis applying to this document) in figures 25 to 27 a safety needle shield comprising a piercing member (132) and a clip (348). The clip defines a first cavity (362), a second leg (356) and a first leg (360) having a second cavity (364) and a distal part (354) engaging a medical device (222). The form of the clip is maintained in both orientations (compare fig. 25 and 26), the movable orientation (see fig. 25) and the binding orientation (see fig. 26).
- 5.3 The subject-matter of corresponding independent claims 20 and 26 differ from the safety needle shield known from the documents D5 and D6 in that the second leg comprises a bearing surface that engages the piercing member and in that the first leg and the second leg are biased for convergent movement such that the first cavity is disposed in the binding orientation and the distal part of the first leg disengages the medical device (for full definition, see corresponding claims 20 and 26).
- 5.4 The problem to be solved by the present invention may be regarded to provide a safety shield that is efficiently manufactured due to a less complicated design (see page 2, paragraph 3).
- 5.5 None of the cited documents hint to the solution as defined in the corresponding independent claims 20 and 26 in order to solve the problem posed.
- 5.6 The solution according to the corresponding independent claims 20 and 26 of the present application is considered as being novel (Article 33(2) PCT), involving an inventive step (Article 33(3) PCT) and being industrially applicable (Article 33(4) PCT).

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International application No.

PCT/US2004/036339

Upon entering the regional phase, the applicant is kindly requested to observe the following:

- 6 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 to D6 is not mentioned in the description, nor are these documents identified therein.
- 7 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 8 Independent claims 1, 15, 20, 26, 27 and 40 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (see corresponding documents D1 to D6) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

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